IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES, *et al.*, *Plaintiffs*, *ex rel.* JEROME PALMIERI, *Relator*, v. ALPHARMA, INC., *et al.*, *Defendants*.	Civil Action No. ELH-10-1601

MEMORANDUM OPINION

Jerome Palmieri, the relator, filed this *qui tam* action on behalf of the United States of America and various individual states (collectively, the "*Qui Tam* States")[1] against his employers, Alpharma, Inc. and Alpharma Pharmaceuticals, LLC (collectively, "Alpharma"); King Pharmaceuticals, Inc. ("King"); and Pfizer, Inc. ("Pfizer"), defendants,[2] pursuant to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq*. and analogous state statutes of the *Qui Tam* States. The suit concerns defendants' marketing of Flector Patch, a topical pain medication delivered by a transdermal patch, approved by the United States Food and Drug Administration ("FDA") for the treatment of acute pain due to "'minor strains, sprains, and contusions.'" Second Amended Complaint ("SAC," ECF 77) ¶ 126 (citation omitted in original).

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[1] The "*Qui Tam* States" are California; Delaware; Florida; Georgia; Hawaii; Illinois; Indiana; Louisiana; Michigan; Montana; Nevada; New Hampshire; New Jersey; New Mexico; New York; Oklahoma; Rhode Island; Tennessee; Texas; and Wisconsin; the Commonwealths of Massachusetts and Virginia; and the District of Columbia.

[2] Alpharma Pharmaceuticals, LLC is a subsidiary of Alpharma, Inc. Through a merger between Alpharma and one of King's subsidiaries, Alpharma became a wholly owned subsidiary of King in December 2008. In October 2010, King merged with Pfizer. *See* Second Amended Complaint (ECF 77) ¶¶ 25-27.

The relator filed his initial Complaint (ECF 2) on April 20, 2010.[3] Pursuant to the initial sealing provisions of the FCA, the suit was filed under seal in order to provide time to the United States and the *Qui Tam* States to decide whether they wished to intervene. *See* 31 U.S.C. § 3730(b)(2).[4] None of the governmental plaintiffs intervened, and the suit was unsealed on July 5, 2011. *See* ECF 20. On October 25, 2011, the relator filed the First Amended Complaint (ECF 43).

The False Claims Act permits a private party, as relator, to sue on behalf of the government to recover damages from defendants who have caused fraudulent claims for payment to be submitted against the public fisc. As an incentive to bring such suits, a successful relator is entitled to share in the government's recovery from the defendants. *See generally ACLU v. Holder*, 673 F.3d 245, 246-51 (4th Cir. 2011) (describing history and current provisions of FCA).[5]

Palmieri alleges that defendants engaged in a program of aggressive and illegal marketing of Flector Patch to physicians, which encouraged physicians, sometimes by way of unlawful "kickbacks," to prescribe Flector Patch to their patients, including prescriptions for "off-label"

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[3] Palmieri filed suit against Alpharma and King in the United States District Court for the Eastern District of Pennsylvania. The United States moved to transfer venue, pursuant to 28 U.S.C. § 1404(a). The relator did not object and the suit was transferred to this district on or about June 11, 2010. The case was reassigned from Judge Catherine C. Blake to me on January 13, 2011. The relator added Pfizer as a defendant in his First Amended Complaint (ECF 43).

[4] The analogous *qui tam* statutes of the *Qui Tam* States also provide for initial filing of a *qui tam* complaint under seal, in order to permit the state to investigate the claim and determine whether it wishes to intervene.

[5] In addition to ordinary federal question jurisdiction, *see* 28 U.S.C. § 1331, the FCA contains a specific grant of subject matter jurisdiction to the federal district courts. *See* 31 U.S.C. § 3732(a). Moreover, a district court with jurisdiction under the FCA also has jurisdiction as to state-law *qui tam* claims "aris[ing] from the same transaction or occurrence." *Id.* § 3732(b).

uses and at excessive dosages. According to the relator, some of the resulting off-label, excessive, or unlawfully-induced prescriptions of Flector Patch were submitted to federal and state health care programs for reimbursement, such as Medicaid and Medicare. However, such programs generally do not permit reimbursement for a medication that is prescribed for a so-called "off-label" use—*i.e.*, a use other than the use for which the medication has been approved by the FDA.

Defendants moved to dismiss the First Amended Complaint. ECF 70. In particular, defendants argued that the "first-to-file" rule, 31 U.S.C. § 3730(b)(5), precluded this Court from exercising subject matter jurisdiction. In addition, they contended that the First Amended Complaint failed to state a claim on which relief could be granted, in light of the heightened pleading requirements applicable to fraud claims under Fed. R. Civ. P. 9(b).

In *United States ex rel. Palmieri v. Alpharma, Inc.*, 928 F. Supp. 2d 840 (D. Md. 2013) (ECF 75, "*Palmieri I*"), I concluded that the first-to-file rule did not bar the relator's claim, but that his allegations failed to meet the Rule 9(b) standard for pleading fraud with particularity. Specifically, the relator's First Amended Complaint failed to identify any particular instance in which an off-label or excessive prescription for Flector Patch was submitted to a government health program for reimbursement. Nor did the First Amended Complaint identify any instances in which doctors to whom defendants allegedly gave illegal kickbacks prescribed Flector Patch to patients covered by government prescription programs. Instead, the relator's charges relied on a crucial factual inference: the First Amended Complaint recounted the total volume of Flector Patch prescriptions submitted to Medicaid and Medicare since 2008, and the amounts of money paid in reimbursements for those prescriptions, to suggest that at least some of these

prescriptions must have been off-label, excessive, or illegally induced prescriptions resulting from defendants' alleged scheme. *See Palmieri I*, 840 F. Supp. 2d at 846. Those allegations, I concluded, plainly failed to meet the Rule 9(b) pleading standard under *United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc.*, 707 F.3d 451 (4th Cir. 2013) (petition for cert. pending). *See Palmieri I*, 928 F. Supp. 2d at 856-57. Nevertheless, I granted leave to amend. *Id.* at 857-58.

On April 2, 2013, the relator filed his Second Amended Complaint. ECF 77. As discussed, *infra*, it includes new allegations regarding prescriptions written for nine patients by two Pennsylvania physicians, Dr. Daniel Rubino and Dr. Kenan Aksu. *See* SAC ¶¶ 275-85.[6]

Defendants again moved to dismiss (ECF 84, the "Motion" or "Mot."), challenging the Second Amended Complaint on three grounds: the "first-to-file" rule under 31 U.S.C. § 3730(b)(5); the Rule 9(b) heightened pleading standard; and the public disclosure bar under 31 U.S.C. § 3730(e)(4)(A).[7] *See* ECF 84. The relator has filed an Opposition (ECF 85, "Opp."), and defendants have filed a Reply (ECF 86). No hearing is necessary to resolve the issues. *See* Local Rule 105.6. For the reasons that follow, I conclude that the Second Amended Complaint fails to state a claim upon which relief can be granted under the Rule 9(b) standard.[8] Therefore, I shall grant the Motion.

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[6] The relator's Second Amended Complaint and Opposition refer to the latter physician as both "Aksu" and "Asku." *Compare* SAC ¶¶ 283-85 and ECF 85 at 9 (using "Aksu") *with* SAC ¶ 284 and ECF 85 at 10 n.5 (using "Asku").

[7] Congress amended the public disclosure bar on March 23, 2010, and the Supreme Court has determined that the amendment is not retroactive. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010).

[8] Because the relator's allegations fail under Rule 9(b), it is unnecessary to reach defendants' arguments concerning the first-to-file rule and the public disclosure bar.

Background[9]

Defendants manufacture and market Flector Patch, a transdermal patch that delivers, via absorption through the patient's skin, a topical application of 1.3% diclofenac epolamine. *See* SAC ¶¶ 88-89. Diclofenac epolamine is a non-steroidal anti-inflammatory drug ("NSAID"), in the same family as ibuprofen and naproxen. *See id.* Flector Patch is the only prescription NSAID topical patch on the market. *Id.* ¶ 89.

The FDA approved Flector Patch for prescription use in December 2007, *id.* ¶ 93, as a "'topical treatment of acute pain due to minor strains, sprains, and contusions.'" *Id.* ¶ 95 (citation omitted in original). However, the use was approved only for up to fourteen days. *Id.* ¶¶ 102, 115-16. Like other NSAIDs, Flector Patch entails risks of cardiovascular and gastrointestinal side effects that increase the longer the drug is used. *Id.* ¶ 91. Therefore, Flector Patch's FDA-approved label contains a warning that a patient should use only "'the lowest effective dose for the shortest duration consistent with individual treatment goals.'" *Id.* (citation omitted in original).

Flector Patch is marketed in Europe under the name "Flector Tissugel," and is approved in Europe for treatment of chronic pain and inflammatory conditions such as osteoarthritis, rheumatoid arthritis, menstrual pain, bursitis, ankylosing spondylitis, and tendonitis. *Id.* ¶ 100. However, defendants have not sought FDA approval for these indications. *Id.*

Palmieri has been employed since 2001 as a sales representative for Alpharma (and later, King and Pfizer), to market defendants' prescription pain medications, including Flector Patch,

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[9] The factual summary is derived from the relator's 118-page Second Amended Complaint. Although *Palmieri I* addressed the relator's First Amended Complaint, I incorporate here by reference all relevant background information contained in *Palmieri I*.

to physicians who treat chronic pain. SAC ¶ 23. As noted, he alleges that defendants engaged in a comprehensive scheme to promote the prescription of Flector Patch for off-label uses and in excessive dosages.

It is salient that federal law does not prohibit a physician from prescribing an approved drug for a non-approved, or "off-label," use. *See* 21 U.S.C. § 396. However, "it is unlawful for a manufacturer to introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and a manufacturer illegally 'misbrands' a drug if the drug's labeling includes information about its unapproved uses." *Washington Legal Found. v. Henney*, 202 F.3d 331, 332-33 (D.C. Cir. 2000) (citing statutes) (internal citations omitted). Furthermore, "a manufacturer's direct advertising or explicit promotion of a product's off-label uses is likely to provoke an FDA misbranding or 'intended use' enforcement action." *Id.* at 333; *see also* 21 C.F.R. § 202.1(e)(4)(ii) (stating that an advertisement for an FDA-approved prescription drug generally "may recommend and suggest the drug only for those uses contained in the [FDA-approved] labeling thereof"). Therefore, the relator contends that defendants' scheme to promote off-label use of Flector Patch was unlawful.

The alleged unlawful scheme had many facets, according to the relator. For one, defendants allegedly instructed their sales representatives to market Flector Patch aggressively to physicians, such as pain management specialists, rheumatologists, and neurologists, who by the nature of their specialties treated only chronic pain and not the acute, localized pain for which Flector Patch was approved. *See* SAC ¶¶ 200-07. In addition, defendants allegedly promoted Flector Patch for continuous use, rather than for short-term use. *See id.* ¶ 212. According to the relator, defendants specifically promoted a 60-patch/30-day prescription as the standard,

appropriate prescription for Flector Patch, despite its FDA approval for usage for up to fourteen days. *See id.* ¶¶ 212-28. Defendants also instructed their sales representatives to discourage shorter prescriptions as "subtherapeutic," and to cease promotional efforts toward physicians, such as emergency room and urgent care physicians, who routinely treat patients for acute pain and who often resisted prescribing Flector Patch at the 60-patch level. *See id.* Defendants also marketed Flector Patch as an alternative to other prescription medications that are FDA-approved only for the treatment of chronic pain. *See id.* ¶¶ 239-54.

In addition, the relator alleges that some of defendants' promotional activities with respect to Flector Patch violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). *See* SAC ¶¶ 305-14. In pertinent part, the Anti-Kickback Statute provides criminal penalties for

> knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.

Id. § 1320a-7b(b)(2)(A).

Specifically, the relator avers that defendants distributed benefits to physicians who were high prescribers of Flector Patch through membership in a "Flector Patch Speakers' Bureau" and "Flector Patch Speaker's Training" program, by which the physicians received paid speaking engagements and access to lucrative referral networks. *See* SAC ¶¶ 138-70.[10] Palmieri also contends that defendants provided samples of Flector Patch to physicians in such a manner as to qualify as "inducements" under the Anti-Kickback Statute. *See* SAC ¶¶ 171-192.

[10] The Second Amended Complaint contains new allegations regarding defendants' promotional efforts with respect to Dr. Daniel Rubino, discussed *infra*. *See* SAC ¶¶ 149-64.

Although Palmieri contends that many of defendants' activities, summarized above, were unlawful, the promotional activities would not, by themselves, violate the False Claims Act or its state law analogs. However, Palmieri also alleges that, by engaging in the conduct described above, defendants knowingly caused false claims to be presented to federal and state government health care programs, in the form of reimbursement claims for prescriptions for off-label uses or for excessive dosages of Flector Patch. The presentment of such claims for payment to government programs constitutes the basis for the relator's assertion of *qui tam* liability.

As indicated, government-funded health care programs generally do not pay for drugs that are prescribed for off-label uses. For instance, the Medicaid program provides funds for health care for low-income persons through a combination of federal and state funding. Federal reimbursement for a prescription drug under Medicaid is limited, with some exceptions, to a drug prescribed for a use for which the drug has been approved by the FDA. *See* 42 U.S.C. § 1396r-8(k)(2)-(3), (6). Moreover, the relator alleges that most states, including the *Qui Tam* States, that provide state funds for reimbursement for prescription drugs under Medicaid limit coverage in the same way. *See* SAC ¶ 53. The same limitation applies to coverage for prescription drugs for the elderly and disabled under the Medicare Part D program. *See* 42 U.S.C. § 1395w-102(e)(4)(A)(ii) (incorporating § 1396r-8(k)(6) by cross-reference). Ordinarily, other programs that provide federal funding for health care also limit prescription drug coverage to usages approved by the FDA. *See* SAC ¶¶ 65-68. The relator contends that defendants caused off-label prescriptions for Flector Patch to be submitted for reimbursement to these government health care programs, thereby causing the presentment of false claims.

Palmieri's allegation that defendants violated the Anti-Kickback Statute constitutes another potential avenue to False Claims Act liability. In March 2010, as part of the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010), the Anti-Kickback Statute was amended to provide expressly that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g) (as amended by § 6402 of PPACA). But, even before this express statutory amendment, some courts had recognized that a violation of the Anti-Kickback Statute could, under some circumstances, form a predicate for FCA liability. *See, e.g., United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 147 F. Supp. 2d 39, 54 (D. Mass. 2001) ("In order for the antikickback violation to be transformed into an actionable FCA claim, the government must have conditioned payment of a claim upon the claimant's certification of compliance with the antikickback provision. That certification may be proven by evidence showing the claimant expressly agreed to abide by the law as a condition of payment. In the absence of an affirmative certification, some courts have found 'implied certification' by virtue of the defendant's participation in the federal program.") (Internal citations omitted).

Of relevance to the Motion, in the Second Amended Complaint the relator has added allegations concerning prescriptions that two Pennsylvania doctors provided to nine patients.[11] In the relator's view, the additional allegations are sufficient to meet the Rule 9(b) standard. Specifically, the relator alleges that for eight Medicare patients, Dr. Rubino prescribed Flector

[11] Although the Second Amended Complaint does not indicate the relator's source of this information, the relator states that he "obtained the information regarding Patients 1 through 9 . . . directly from the offices of Dr. Rubino and Dr. Asku themselves." Opp. at 10 n.5.

Patch off-label and, "upon information and belief," these eight persons "filled their prescriptions which were submitted to Medicare for payment because they returned to Dr. Rubino for one or more refills." SAC ¶ 274. Similarly, the relator alleges that a Medicare patient of Dr. Aksu received an off-label Flector Patch prescription and, based on a subsequent refill request, it would have been submitted to Medicare for reimbursement. *See id.* ¶ 285.

For instance, the relator describes one patient, referred to as "Patient 1," who saw Dr. Rubino on March 3, 2008, "suffering from chronic pain, including back pain caused by degenerative joint disease in the lumbar region that was worse than usual, as well as pain in the right shoulder." SAC ¶ 275. Dr. Rubino provided Patient 1 with a sample of Flector Patch. The relator further alleges, *id.*:

> On April 1, 2008, Patient 1 returned, with continuing lower back pain caused by the patient's chronic condition. Dr. Rubino gave the patient a 60 patch Flector Patch prescription with three refills. This prescription was off-label because Patient 1 had chronic pain and not the "minor sprains, strains, and contusions" covered by Flector Patch's indication. Patient 1 returned on April 29, 2008 and received yet another 60 Flector Patch prescription with three refills, showing that Patient 1 had submitted the prior off-label prescription to Medicare for payment and needed an additional prescription.

Patient 1, who allegedly remained on Medicare, returned on August 18, 2011, and "received an additional off-label 60 patch Flector Patch prescription with three refills from Dr. Rubino." *Id.* ¶ 276 (adding that the "prescription was phoned into Patient 1's pharmacy, Giant Pharmacy").

The relator supplies further allegations that, in his view, establish that Patient 1 sought Medicare reimbursement, *id.* ¶ 277:

> On October 11, 2011, Patient 1 could not make the appointment with Dr. Rubino that month because Patient 1 had no money for gas. On November 4, 2011, Patient 1, still on Medicare, returned to Dr. Rubino saying that the patient needed to lower expenses but still requested a refill of the 60 Flector Patch prescription. Upon information and belief, Patient 1 therefore did not pay out-of-pocket for the

> prescribed Flector Patches (which would be upwards of $400 for each prescription), but rather bills for those patches – whose prescriptions were caused by Defendants' off-label marketing – were presented by the pharmacy to Medicare for payment.

In addition, the relator identifies seven other Medicare patients of Dr. Rubino who are alleged to have received off-label Flector Patch prescriptions. *See id.* ¶¶ 278-282. He provides the dates on which Dr. Rubino allegedly saw these eight patients and infers that, because Patients 1, 2, 4, and 5 were prescribed Flector Patch on at least two occasions, they filled at least one of those prescriptions and submitted claims to Medicare for reimbursement. *See id.* ¶¶ 275-282. With respect to Patient 4, the relator alleges that the individual's prescriptions were filled at a Walgreens pharmacy. *See id.* ¶ 280.

Additional facts will be presented in the Discussion.

Discussion

Defendants assert, *inter alia*, that the Second Amended Complaint fails to state a claim upon which relief can be granted. Their argument arises under Rule 12(b)(6) of the Federal Rules of Civil Procedure, and implicates the pleading standard for all civil actions under Fed. R. Civ. P. 8, as well as the heightened standard for fraud claims under Fed. R. Civ. P. 9(b).

A. Standard of Review

A defendant may test the adequacy of a complaint by way of a motion to dismiss under Rule 12(b)(6). *See, e.g.*, *Davani v. Va. Dept. of Transp.*, 434 F.3d 712, 720 (4th Cir. 2006). In the first instance, whether a complaint states a claim for relief is judged by reference to the pleading requirements of Fed. R. Civ. P. 8(a)(2). It provides that a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." The

purpose of the Rule is to provide the defendant with "fair notice" of the claim and the "grounds" for entitlement to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 n.3 (2007).

Both *Twombly*, 550 U.S. 544, and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), make clear that, in order to survive a motion to dismiss under Rule 12(b)(6), a complaint must contain facts sufficient to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570; *see Iqbal*, 556 U.S. at 684 ("Our decision in Twombly expounded the pleading standard for 'all civil actions'. . . ."); *see also, e.g.*, *Simmons v. United Mortg. & Loan Inv.*, 634 F.3d 754, 768 (4th Cir. 2011); *Andrew v. Clark*, 561 F.3d 261, 266 (4th Cir. 2009); *Giarratano v. Johnson*, 521 F.3d 298, 302 (4th Cir. 2008). A plaintiff need not include "detailed factual allegations" in order to satisfy Rule 8(a)(2). *Twombly*, 550 U.S. at 555. However, the Rule demands more than bald accusations or mere speculation. *Id.* To satisfy the minimal requirements of Rule 8(a)(2), the complaint must set forth "enough factual matter (taken as true) to suggest" a cognizable cause of action, "even if . . . [the] actual proof of those facts is improbable and . . . recovery is very remote and unlikely." *Id.* at 556. A complaint that provides no more than "labels and conclusions," or "a formulaic recitation of the elements of a cause of action," is insufficient. *Id.* at 555.

In reviewing a Rule 12(b)(6) motion, a court "'must accept as true all of the factual allegations contained in the complaint,'" and must "'draw all reasonable inferences [from those facts] in favor of the plaintiff.'" *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 440 (4th Cir. 2011) (citations omitted). However, a motion pursuant to Rule 12(b)(6) typically "does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses," *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999)

(internal quotation marks omitted), unless such a defense can be resolved on the basis of the facts alleged in the complaint. Moreover, the court is not required to accept legal conclusions drawn from the facts. *See Papasan v. Allain*, 478 U.S. 265, 286 (1986); *Monroe v. City of Charlottesville*, 579 F.3d 380, 385-86 (4th Cir. 2009), *cert. denied*, 130 S.Ct. 1740 (2010). If the "well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct," the complaint has not shown that "'the pleader is entitled to relief.'" *Iqbal*, 556 U.S. at 679 (citation omitted).

"Ordinarily, a court may not consider any documents that are outside of the complaint, or not expressly incorporated therein, on a motion to dismiss" under Rule 12(b)(6). *Clatterbuck v. City of Charlottesville*, 708 F.3d 549, 557 (4th Cir. 2013). In considering a motion under Rule 12(b)(6), however, the court may properly consider documents "attached or incorporated into the complaint," *E.I. du Pont de Nemours & Co.*, 637 F.3d at 448, as well as documents "attached to the motion to dismiss, so long as they are integral to the complaint and authentic." *Philips v. Pitt Cnty. Mem'l Hosp.*, 572 F.3d 176, 180 (4th Cir. 2009).

Suits brought under the False Claims Act sound in fraud, and thus are "subject to Federal Rule of Civil Procedure 9(b), which requires that claimants plead fraud with particularity." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783-84 (4th Cir. 1999). In addition, "Rule 9(b)'s heightened pleading standard applies to state law fraud claims asserted in federal court." *N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 13 (1st Cir. 2009). Therefore, a Rule 9(b) analysis governs the relator's state law *qui tam* claims as well as his claims under the FCA.

Rule 9(b) states: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Under the rule, a plaintiff alleging claims that sound in fraud "'must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.'" *United States ex rel. Owens v. First Kuwaiti Gen'l Trading & Contracting Co.*, 612 F.3d 724, 731 (4th Cir. 2010) (citation omitted); *see also Harrison*, 176 F.3d at 784. In other words, "'Rule 9(b) requires plaintiffs to plead the who, what, when, where, and how: the first paragraph of any newspaper story.'" *Crest Constr. II, Inc. v. Doe*, 660 F.3d 346, 353 (8th Cir. 2011) (citation omitted).

Rule 9(b) serves several purposes:

> "First, the rule ensures that the defendant has sufficient information to formulate a defense by putting it on notice of the conduct complained of. . . . Second, Rule 9(b) exists to protect defendants from frivolous suits. A third reason for the rule is to eliminate fraud actions in which all the facts are learned after discovery. Finally, Rule 9(b) protects defendants from harm to their goodwill and reputation."

Harrison, 176 F.3d at 784 (citation omitted).

"A court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." *Id.* Nevertheless, the "'clear intent of Rule 9(b) is to eliminate fraud actions in which all the facts are learned through discovery after the complaint is filed.'" *Id.* at 789 (citation omitted); *see U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 380 (4th Cir. 2008) ("[I]f allowed to go forward, Relators' FCA claim would have to rest primarily on

facts learned through the costly process of discovery. This is precisely what Rule 9(b) seeks to prevent.").

B. Pleading of Particular False Claims

Defendants maintain that the Second Amended Complaint fails to meet the Rule 9(b) standard because the relator still does not adequately allege details of any false claims submitted to the government. They acknowledge that the relator has added allegations that nine patients of two Pennsylvania doctors received off-label prescriptions. Nevertheless, defendants contend that the relator fails adequately to allege that claims for reimbursement for those prescriptions were submitted to federally-funded health care programs, and thus they insist that the relator's claims must fail. The relator counters that his allegations are sufficient to withstand dismissal.

As in *Palmieri I*, the relevant standards are found in the Fourth Circuit's decision in *United States ex rel. Nathan v. Takeda Pharmaceuticals of North America, Inc.*, *supra*, 707 F.3d 451. Like Palmieri, the relator in *Nathan* alleged a false claim violation arising out of a scheme to promote a prescription drug, Kapidex, for off-label use. Indeed, the alleged Kapidex marketing scheme was remarkably similar to the scheme to promote Flector Patch that is alleged here: "The identified marketing practices were: (1) Takeda's promotion of Kapidex to rheumatologists, who typically do not treat patients having conditions for which Kapidex has been approved; and (2) Takeda's practice of marketing high doses of Kapidex for the treatment of conditions for which only a lower dose has been approved by the FDA." *Nathan*, 707 F.3d at 454. The district court dismissed the claim and the Fourth Circuit affirmed.

The *Nathan* Court squarely rejected the relator's argument seeking "a more lenient application" of Rule 9(b), explaining: "We have adhered firmly to the strictures of Rule 9(b) in

applying its terms to cases brought under the Act." *Id.* at 456. The Court noted that, under the FCA, "the critical question is whether the defendant caused a false claim to be presented to the government, because liability under the Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme." *Id.* at 456. Citing *United States ex rel. Clausen v. Laboratory Corp. of America, Inc.*, 290 F.3d 1301 (11th Cir. 2002), the *Nathan* Court continued: "Therefore, when a relator fails to plead plausible allegations of presentment, the relator has not alleged all the elements of a claim under the Act." *Id.*

Disavowing the contrary views of other circuits as to a lenient pleading standard, the Fourth Court said: "To the extent that other cases apply a more relaxed construction of Rule 9(b) in such circumstances, we disagree with that approach." *Id.* at 457-58.[12] Encapsulating its holding, the *Nathan* Court concluded: "[W]hen a defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment." *Id.* at 457 (emphasis in original).

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[12] As I noted in *Palmieri I*, 928 F. Supp. 2d at 854-55, the Fourth Circuit "expressly adopted the position staked out by the Eleventh Circuit in *Clausen*" while rejecting a "more lenient pleading standard" similar to those adopted by several other circuits. *See, e.g., United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 29 (1st Cir. 2009) (stating that "a relator could satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim") (citation omitted); *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) ("Since a relator is unlikely to have [billing] documents unless he works in the defendant's accounting department, [a requirement to allege specific false claims] takes a big bite out of *qui tam* litigation. . . . [M]uch knowledge is inferential . . . and the inference that [the relator] proposes is a plausible one."); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (holding that a complaint that does not allege "details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted").

Of import here, the *Nathan* Court readily "acknowledge[d] the practical challenges that a relator may face in cases such as the present one, in which a relator may not have independent access to records such as prescription invoices, and where privacy laws may pose a barrier to obtaining such information without court involvement." *Id.* at 458. Nevertheless, the Court observed that such barriers do not reduce a relator's burden to allege "facts that support all the elements of a claim." *Id. See also, e.g., Clausen*, 290 F.3d at 1312 n.21 ("We cannot make assumptions about a False Claims Act defendant's submission of actual claims to the Government without stripping all meaning from Rule 9(b)'s requirement of specificity or ignoring that the true essence of the fraud of a False Claims Act action involves an actual claim for payment and not just a preparatory scheme.") (Quotation marks omitted).

The *Nathan* Court's reasoning as to the allegations at issue supplies further guidance. In that complaint, the relator had identified two physicians "who averred that they prescribed 60 mg dosages of Kapidex to treat [a particular condition] in Medicare patients and were unaware that the drug was available in a 30 mg dosage due to Takeda's sampling practices." 707 F.3d at 460. Yet, the Fourth Circuit concluded that those allegations were insufficiently specific. It said, *id.* (emphasis added):

> [T]he amended complaint does not include any details about the particular prescriptions these physicians wrote for Medicare patients, such as approximate dates or patient information, nor does the amended complaint contain allegations that the Medicare patients ever "filled" these prescriptions *or that corresponding claims for reimbursement ever were submitted to the government.*

The Fourth Circuit made clear its reluctance to infer the submission of a false claim to the government, *id.* (emphasis added):

> As previously discussed, *liability under the Act attaches only to false claims actually submitted to the government for reimbursement*. General

> allegations such as those made here, that unidentified Medicare patients received prescriptions for off-label uses, do not identify with particularity any claims that would trigger liability under the Act. In the absence of the required specific allegations, *a court is unable to infer that a Medicare patient who has received a prescription for an off-label use actually filled the prescription and sought reimbursement from the government.* Indeed, "[i]t may be that physicians prescribed [the drug] for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it." [*United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007), *overruled on other grounds by Allison Engine Co. v. United ex rel. Sanders*, 553 U.S. 662 (2008).] *We therefore disagree with Relator's assertion that, if a patient is insured under a government program, we reasonably may infer that any prescription the patient received for an off-label use was filled and that a claim was presented to the government*.

The *Nathan* Court plainly indicated that, when allegations concerning Medicare patients "do not identify *with particularity any claims* that would trigger liability under the [FCA,]" a court is "unable" to infer either that the prescription was filled or that a claim for reimbursement was submitted to a government-funded health care program. *See id*.

Applying the standards set forth in *Nathan*, Palmieri's new allegations in the Second Amended Complaint still fall short of alleging the presentment of an actual false claim for reimbursement that was submitted to the government. To be sure, by citing four patients' requests for refills, the relator plausibly alleges that those patients did fill prior prescriptions. Nevertheless, the relator does not know the actual identity of those individuals, and his allegations are plainly lacking in details such as the actual amount of any claim for reimbursement, the identity of any individual who submitted a claim, or the date on which any request for reimbursement was made. Moreover, the relator's allegations are still devoid of the most critical component, which the *Nathan* Court made clear cannot be inferred: "that corresponding claims for reimbursement ever were submitted to the government." *Id.* at 460.

The relator insists that his allegations are sufficient because the only "reasonable inference" to be drawn is that Medicare patients must have submitted prescriptions to the government for reimbursement. *See* Opp. at 1, 5-6; *see also id.* at 2. For example, the relator explains that Patient 1 could not make an appointment on one instance because that individual had no money for gas, and later sought "to lower expenses" while still requesting a Flector Patch refill. *See* SAC ¶ 277.

As noted, the Fourth Circuit explicitly endorsed the notion, articulated previously by the First Circuit, that "'[i]t may be that physicians prescribed [the drug] for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it.'" *Nathan*, 707 F.3d at 460 (quoting *Rost*, 507 F.3d at 733). Although the First Circuit adheres to a more lenient Rule 9(b) standard, it observed in *Rost*, 507 F.3d at 733: "It may well be that doctors who prescribed [the drug] for off-label uses as a result of [defendant's] illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients."[13] Specific allegations about an individual patient's financial situation at a particular point cannot substitute for a well-pleaded allegation of the actual submission of a false claim for reimbursement.

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[13] The First Circuit has said:

> In a qui tam action in which the defendant is alleged to have induced third parties to file false claims with the government, a relator can satisfy this requirement by "providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim."

United States ex rel. Ge v. Takeda Pharmaceutical Co. Ltd., 737 F.3d 116, 123-24 (1st Cir. 2013) (quoting *Duxbury*, 579 F.3d at 29 (quoting *Rost*, 507 F.3d at 733)). Nevertheless, as *Rost* reflects, even the First Circuit has proven reluctant to infer that claims were submitted for government reimbursement, absent sufficient allegations that establish as much.

The relator's argument also misstates the applicable standard derived from *Nathan*. Contrary to the relator's portrayal, the *Nathan* Court ruled that "when a defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator *must allege with particularity that specific false claims actually were presented to the government* for payment." *Id.* at 457 (last emphasis added). Indeed, the Court expressly rejected the relator's invitation to infer that, where a government-insured patient receives a prescription, that prescription must have been filled and a claim for reimbursement must have been submitted to the government. *See id.* at 460; *see also id.* at 461 (rejecting argument that false claims must have been presented to government because "federally insured patients received off-label prescriptions" as "inherently speculative in nature").

The so-called "donut hole" in Medicare Part D coverage illustrates why a prescription provided to a Medicare patient does not necessarily result in the submission of a reimbursement claim to the government.[14] Under Part D, which applies to prescription drug coverage, the government provides reimbursement, but only up to an initial drug coverage limit. 42 U.S.C. § 1395w-102(b)(3)(A). Medicare also provides catastrophic coverage, including for prescription medication, but does so only above a certain, higher threshold. *Id.* § 1395w-102(b)(4). Accordingly, Medicare recipients who have exceeded the initial coverage limit for prescription medication, but who have not yet reached the catastrophic coverage threshold, fall within a "donut hole," in which the government does not reimburse for the cost of prescription drugs. In

[14] The parties have not discussed the "donut hole" and I am unaware of any cases addressing this Medicare coverage gap in the context of the False Claims Act.

effect, while a Medicare recipient is in the "donut hole," her or she lacks prescription drug coverage from the government. *See, e.g., Kopstein v. Independence Blue Cross*, 339 F. App'x 261, 262 n.1 (3d Cir. 2009) (explaining the "donut hole"). Any of the Medicare patients to whom the relator refers might have been in the coverage gap at the time the relevant prescriptions were issued or filled. If so, their prescription claims might not have been submitted to Medicare, as the government would not have provided coverage for them.

As the relator concedes, he "does not have Medicare's reimbursement details," Opp. at 1-2, and can allege based upon nothing more than "information and belief" that patients filled prescriptions that were then "submitted to Medicare for payment." SAC ¶ 274; *see also id.* ¶ 277 ("Upon information and belief," pharmacy presented Patient 1's bill for prescription to Medicare for payment); ¶ 281 ("upon information and belief," Patient 5 submitted claim to MEDCO for Medicare reimbursement). However, courts have cautioned against reliance on information-and-belief pleading in the False Claims Act context. *See Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1013-14 (11th Cir. 2005) (finding that allegations based on "information and belief" did not provide an "indicia of reliability" as to the actual submission of fraudulent claims); *see also, e.g., United States ex rel. Seal 1 v. Lockheed Martin Corp.*, 429 F. App'x 818, 820 (11th Cir. 2011) (rejecting allegations pleaded "on information and belief" that defendant submitted bills for payment to government and that government paid those claims); *Clausen*, 290 F.3d at 1310-11 (where Rule 9(b) applies, "pleadings generally cannot be based on information and belief") (citations and quotation marks omitted).

Significantly, this is not an instance in which flexibility is warranted under Rule 9(b) on the ground that information sufficient to identify individual patients is in the possession of a

defendant. The relator asserts that the identities of the nine patients referenced in the Second Amended Complaint could be ascertained through the records of the two doctors. Opp. at 10 n.5. However, as defendants note, the case on which the relator relies pertains to information found in defendants' *own* possession. *See United States ex rel. Shank v. Lewis Enterprises, Inc.*, 2006 WL 1207005, at *5 (S.D. Ill., May 3, 2006); *see also, e.g.*, *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003) ("'[C]ourts have held that [Rule 9(b)] may be relaxed where information is *only* within the opposing party's knowledge.'") (citation omitted; emphasis added in *Yuhasz*); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997) (affirming dismissal and explaining that although "information and belief" may be sufficient where "the facts relating to the alleged fraud are peculiarly *within the perpetrator's knowledge*," it cannot grant "'license to base claims of fraud on speculation and conclusory allegations'") (emphasis added; citation omitted).

To be sure, the *Nathan* Court cautioned that the standard it adopted "does not foreclose claims under the [FCA] when a relator plausibly pleads that specific, identifiable claims actually were presented to the government for payment." *Id*. at 458. And whether the "factual allegations in a given case meet the required standard must be evaluated on a case-specific basis." *Id*. The problem for the relator is that his allegations still require the Court to draw inferences of the very sort that the Fourth Circuit rejected in *Nathan*.

The decision of the Eleventh Circuit in *United States ex rel. Clausen, supra*, 290 F.3d 1301, on which the Fourth Circuit relied in *Nathan*, is also instructive. In the suit, Clausen described in detail the alleged fraudulent scheme, but failed to provide "any billing information to support [Clausen's] allegation that actual false claims were submitted for payment." 290 F.3d

at 1306. Nowhere in the complaint, the Eleventh Circuit emphasized, "can one find any allegation, stated with particularity, of a false claim actually being submitted to the Government." *Id.* at 1312. Although the relator provided "details of [the] medical treatment" provided to one patient, he "offer[ed] no factual basis for the conclusory allegation that LabCorp submitted actual improper claims for payment to the Government on the 'date of service or within a few days thereafter.'" *Id.* at 1312 (quoting complaint). *See also id.* at 1316 n.2 (Barkett, J., dissenting) (noting that "in paragraph 60 of his complaint, Clausen alleges that LabCorp performed an unnecessary Glucose test on patient H.L. on April 15, 1997, and that a claim for the test was submitted 'on April 15 or within a few days thereafter' via electronic form HCFA 1500, with CPT code 82947"). Because Clausen's allegations "failed to meet the minimum pleading requirements for the actual presentment of any false claims," the Eleventh Circuit affirmed the dismissal of his claims under Rule 9(b). *Id.* at 1315. Here, as in *Clausen*, the relator offered certain details concerning individual patients, but failed to provide any "copies of a single actual bill or claim or payment"; any "amounts of any charges"; any "actual dates of claims" submitted to the government; or any completed claim forms. *See id.* at 1306.

United States ex rel. Atkins v. McInteer, 470 F.3d 1350 (11th Cir. 2006), is similarly informative. There, the relator identified "particular patients, dates and corresponding medical records for services that he contends were not eligible for government reimbursement," but then "fail[ed] to provide the next link in the FCA liability chain: showing that the defendants *actually submitted* reimbursement claims for the services he describes." *Id.* at 1359. Such allegations, the Eleventh Circuit concluded, were insufficient to withstand dismissal under Rule 9(b). *See id.* at 1359-60; *see also, e.g., Corsello*, 428 F.3d at 1014 ("In short, Corsello provided the 'who,'

'what,' 'where,' 'when,' and 'how' of improper practices, but he failed to allege the 'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government.").

In an effort to explain limitations on the information found in the Second Amended Complaint, Palmieri invokes privacy concerns. In particular, he avers that, in order "[t]o comply with the privacy restrictions of the Health Insurance Portability and Accountability Act of 1996 ('HIPAA'), 42 U.S.C. § 1320d *et seq.*, all identifying information has been omitted from the descriptions of the patients included in the [Second Amended] Complaint." SAC ¶ 275 n.14. However, this is not a case in which the relator knows the identity of the patients who received an off-label prescription and sought federal reimbursement but, based on privacy concerns, omitted from the complaint the information known to him. Rather, Palmieri admits that he "obtained the information regarding Patients 1 through 9 . . . directly from the offices of Dr. Rubino and Dr. Asku themselves." Opp. at 10 n.5. And, he observes that "the doctors who wrote the prescriptions and the pharmacies who dispensed them" are "subject to HIPAA restrictions," and therefore "the patient names could not, by law, be provided to Palmieri." *Id.*[15] In other words, the relator concedes that he does not know the identities of any of the nine patients and that he was prohibited, under HIPAA, from learning their identities through the two doctors, who were his sole sources of that information.

[15] As the relator acknowledges, *see* Opp. at 10 n.5, it is not obvious that he is subject to HIPAA restrictions. *See, e.g.*, *United States v. Boston Scientific Neuromodulation Corp.*, 2013 WL 2404816, at *7 (D.N.J. May 31, 2013) (noting that HIPAA privacy regulations apply to three types of "covered entities": (1) health care providers; (2) health plans, such as insurers and HMOs; and (3) clearinghouses) (citing 45 C.F.R. §§ 160.102 and 160.103). Moreover, it does not appear that the relator asked the medical providers to attempt to obtain HIPAA waivers from their patients.

As discussed, in *Nathan* the Fourth Circuit recognized that "a relator may not have independent access to records such as prescription invoices" and that "privacy laws may pose a barrier to obtaining such information without court involvement." 707 F.3d at 458. "Nevertheless," the Court said, "our pleading requirements do not permit a relator to bring an action without pleading facts that support all the elements of a claim." *Id.* Similarly, in *United States ex rel. McDermott v. Genentech, Inc.*, 2006 WL 3741920, at *12 (D. Me. Dec. 14, 2006), the district court emphasized that "HIPAA does not preclude a health care provider from disclosing the 'what, when and where of specific claims for medical reimbursement,' so long as the patient is not identified or identifiable as a result of the disclosure," and added that any "difficulty [a relator] might encounter in obtaining such information is not reason enough to ignore" First Circuit precedent establishing the particularity requirement.

It is also noteworthy that *qui tam* relators routinely use the initials of patients, in an effort to respect privacy concerns while complying with Rule 9(b)'s particularity requirement. *See, e.g., United States ex rel. Heineman-Guta v. Guidant Corp.*, 718 F.3d 28, 33 (1st Cir. 2013) (complaint included "the initials of the patients who received implantations due to the purported scheme and the dates and places of implantation"); *Corsello*, 428 F.3d at 1013 (relator's "complaint provided the initials of patients whose Medicare forms were improperly completed" and allegedly submitted); *United States ex rel. Michaels v. Agape Senior Cmty. Inc.*, 2013 WL 6383085, at *2 (D.S.C. Dec. 5, 2013) (observing that the plaintiffs "made genuine efforts to balance those competing concerns by providing more detail in amended complaints, while also using initials of—not names of—patients"); *see also United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 555 (8th Cir. 2006) (noting that relator had offered a table and

allegations that "indicate the time, surgeon, patient initials, and [nurse anesthetist] who performed anesthesia services"); *Clausen*, 290 F.3d at 1304 (prior complaint's allegations included, *inter alia*, "the testing histories of three patients identified by their initials (H.L., L.W. and M.A.)").

Without direct access to information concerning the submission of false claims to the government, the relator has relied on information provided to him by two doctors' offices and asks the Court to infer, based on that information, that either patients or pharmacies subsequently submitted claims for reimbursement to the government. In my view, the relator's revised allegations cannot be reconciled with *Nathan* and the pleading requirements of Rule 9(b).[16]

Unlike this case, *Nathan* apparently did not involve allegations of violations of the Anti-Kickback Statute. However, Palmieri's charges concerning the Anti-Kickback Statute suffer from the same fatal flaw as his other *qui tam* allegations: although the relator alleges an illegal scheme that could have resulted in the submission of false claims to the government, he does not provide details of any false claim that actually was submitted.

[16] Like defendants here, *see* Mem. at 12-14, the defendant in *Nathan* had also argued that the relator failed to state a plausible claim of causation. In other words, in addition to arguing that the relator did not sufficiently allege the *submission* of false claims, the defendant in *Nathan* argued that the relator failed to state a plausible claim that the defendant *caused* such submissions. In light of its conclusion that the relator failed to allege sufficiently that any false claims were presented, the Fourth Circuit did "not reach the additional question whether Relator alleged sufficient facts to support the required causation element for a claim asserted under the Act." *Nathan*, 707 F.3d at 455. For the same reason, I need not reach defendants' arguments as to causation. Nor is it necessary to address defendants' contention that the prescriptions identified by the relator were not necessarily off-label. *See* Mem. at 9-11 & n.4.

C. With or Without Prejudice

The only remaining question is whether dismissal of the Second Amended Complaint should be with or without prejudice. In their Motion, defendants seek dismissal with prejudice, Mot. at 1, 2, and the relator has not asked for further leave to amend. Rather, his only request is that his state law claims, which both sides agree are co-extensive with his federal claims, be dismissed without prejudice. Opp. at 25. In the Reply, defendants do not specifically address that issue. As noted, courts have adopted differing approaches to the Rule 9(b) standard in the context of the federal False Claims Act, and it is conceivable that the relator's state law claims could prove viable under a more lenient standard found to be applicable to those claims. In light of those considerations, I will dismiss the state law claims, without prejudice.

Conclusion

Nathan is binding Circuit precedent and, in my view, it is completely dispositive here. It dictates that the Second Amended Complaint must be dismissed for failure to state a claim upon which relief may be granted.

A separate Order follows, consistent with this Memorandum Opinion.

Date: March 21, 2014

/s/
Ellen Lipton Hollander
United States District Judge